UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WISCONSIN

JILL A. WHITCOMB,

Plaintiff,

v. **Case No. 13-CV-990**

SYLVIA MATHEWS BURWELL,

Defendant.

DECISION AND ORDER

This action comes before the court for review of the Secretary of Health and Human Services's final decision denying coverage for a continuous glucose monitor for plaintiff Jill Whitcomb. All parties have consented to the full jurisdiction of a magistrate judge. (ECF Nos. 42, 43.) The court has subject matter jurisdiction and venue is proper under 42 U.S.C. §§ 405(g) and 1395ff(b).

I. Standard of Review

Judicial review of a final decision of the Secretary of Health and Human Services proceeds in accordance with 42 U.S.C. § 405(g), *see* 42 U.S.C. § 1395ff(b), in the same manner as the court reviews a final decision of the Commissioner of the Social Security Administration. *Heckler v. Ringer*, 466 U.S. 602, 605 (1984). The factual findings of the

Secretary are conclusive if supported by substantial evidence. 42 C.F.R. § 405.1136(f). Legal questions are reviewed only to determine whether the Secretary complied with the law and whether that law is valid. *Wood v. Thompson*, 246 F.3d 1026, 1029 (7th Cir. 2001) (quoting *Johnson v. Heckler*, 741 F.2d 948, 952 (7th Cir. 1984)). In assessing whether the Secretary complied with the law, the court affords deference to the Secretary's construction of the agency's own regulations or its governing statutes. *Thomas Jefferson Univ. v. Shalala*, 512 U.S. 504, 512 (1994); *Wood*, 246 F.3d at 1030 (citing *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842 (1984)).

II. General Background of the Medicare Program

Medicare is a defined benefit program, 64 Fed. Reg. 22619, 22620, that generally precludes coverage for items or services that "are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). The Secretary administers the Medicare program through the Centers for Medicare & Medicaid Services (CMS) and is vested with authority to decide whether an item or service is "reasonable and necessary" or is otherwise covered under one of the broad coverage categories under the Medicare Act, 64 Fed. Reg. 22619, 22620. CMS contracts out many administrative functions, including payment, to private organizations, called Medicare Administrative Contractors (MACs).

A National Coverage Determination (NCD) is "a determination by the Secretary that a particular item or service is covered nationally by Medicare." 42 C.F.R.

§ 405.1060(a)(1). An MAC may, by way of a Local Coverage Determination (LCD), make its own determination as to whether an item or service is reasonable and necessary—and, therefore, covered by Medicare. *See* 42 U.S.C. § 1395ff(f)(2)(B). However, an LCD may not conflict with an NCD. Such a determination is binding throughout that contractor's jurisdiction. *Almy v. Sebelius*, 749 F. Supp. 2d 315, 320 (D. Md. 2010) (citing 42 U.S.C. § 1395ff(f)(2)(B)).

Prior to the Benefits Improvement and Protection Act of 2000 (BIPA), Pub. L. 106-554, the information now contained in LCDs was contained in Local Medical Review Policies (LMRPs). In addition to information as to whether an item or service was covered by Medicare, LMRPs could contain non-coverage information, such as the code that should be used to bill for a service or item and what payment was associated with a particular service or item. BIPA replaced LMRPs with LCDs. *See* 67 Fed. Reg. 54534, 54536. LCDs contain information only as to whether an item or service is reasonable and necessary and, therefore, covered by Medicare. *Id.* Following BIPA, payment and coding information is now set forth in Policy Articles (Articles). Thus,

> [a] local policy may consist of two separate, though closely related documents: the LCD and an associated article. The LCD only contains reasonable and necessary language. Any non-reasonable and necessary language a Medicare contractor wishes to communicate to providers may be done through the article. At the end of an LCD that has an associated article, there is a link to the related article and vice versa.

Centers for Medicare and Medicaid Services, http://www.cms.gov/medicare-coverage-database/ (last visited May 26, 2015); *see also* CMS Medicare Manual System, Pub. 100-8,

Medicare Program Integrity Manual, Chapter 3 - Verifying Potential Errors and Taking Corrective Actions, § 3.3.2.8 – MAC Articles, available at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c03.pdf) (last visited May 26, 2015). Absent a published determination regarding whether a certain item or service is covered by Medicare, coverage "decisions are made based on the individual's particular factual situation," 68 Fed. Reg. 63692, 63693 (citing *Heckler v. Ringer*, 466 U.S. 602, 617 (1984)), and whether the item or service is reasonable and necessary, *Almy*, 749 F. Supp. 2d at 320.

Coverage determinations set forth in an NCD or LCD may be challenged in accordance with 42 U.S.C. § 1395ff(f). *See also* 42 C.F.R. Part 426. Whitcomb did not pursue this path. (Tr. 28.) Instead, this action comes before the court under 42 U.S.C. § 1395ff(b) pursuant to which the issue is the propriety of the Secretary's decision in Whitcomb's particular case.

III. Glucose Monitors

Glucose monitors covered by Medicare are discussed in NCD 40.2, which states in part:

> Blood glucose monitors are meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood. The patient, using a disposable sterile lancet, draws a drop of blood, places it on a reagent strip and, following instructions which may vary with the device used, inserts it into the device to obtain a reading. Lancets, reagent strips, and other supplies necessary for the proper functioning of the device are also covered for patients whom the device is indicated. Home blood glucose monitors enable certain patients

> to better control their blood glucose levels by frequently checking and appropriately contacting their attending physician for advice and treatment.

In addition to NCD 40.2, applicable to this case there is a Local Coverage Decision that addresses glucose monitors. Like NCD 40.2, LCD L27231 focuses on metered blood glucose monitors that require a beneficiary to place a blood sample on a reagent strip before placing it into the monitoring device to be read.

IV. Whitcomb Seeks Coverage for a Continuous Glucose Monitor

Whitcomb is an enrollee of United Healthcare of Wisconsin/Secure Horizons's Medicare Advantage plan. (Tr. 5.) For the past 35 years, Whitcomb has suffered from type 1 diabetes. (Tr. 144, 146.) Due to the nature of her symptoms, the nurse practitioner primarily responsible for providing care for Whitcomb regarding the management of her diabetes prescribed a continuous glucose monitor for Whitcomb. (Tr. 830-37.) A continuous glucose monitor is a sensor system that is designed to continuously and automatically monitor interstitial glucose values in subcutaneous tissue. (Tr. 830-34.) After a successful six-month trial period with the monitor (Tr. 281-98), Whitcomb requested that United provide coverage for a continuous glucose monitor (Tr. 47).

United denied her request, citing Article A47238, which states "Continuous glucose monitors…are considered precautionary and therefore non-covered under the DME benefit." (Tr. 56.) That conclusion was affirmed by United upon further review (Tr. 266-67) and by a qualified independent contractor (Tr. 196-97). Whitcomb requested

a hearing before an administrative law judge (ALJ), and a hearing was held on January 17, 2013. (Tr. 816-57.) On February 6, 2013, the ALJ issued a decision fully favorable to Whitcomb, concluding that a continuous glucose monitor was covered under NCD 40.2 and LCD L27231. (Tr. 68-78.) United appealed and on August 25, 2013, the Medicare Appeals Council reversed the ALJ's decision. (Tr. 18-29.) The Council concluded that the NCD referred to only blood glucose monitors that determine blood glucose reading after a beneficiary draws a drop of blood from the finger with a sterile lancet, places it on a specially treated reagent strip, and inserts the strip into the blood glucose monitor for the reading. (Tr. 27.) The LCD, the Council concluded, incorporates Article A47238, which unambiguously states that continuous glucose monitors are not covered by Medicare. (Tr. 27.) The present action followed.

V. Analysis

The parties agree that NCD 40.2 and LCD L27231 do not explicitly refer to continuous glucose monitors. But they disagree as to the meaning of that silence. Whitcomb contends that NCD 40.2 and LCD L27231 discuss glucose monitors generally and, thus, necessarily include continuous glucose monitors. (ECF No. 48 at 19.) The Secretary argues that NCD 40.2 and LCD L27231 are limited to metered glucose monitors that require a beneficiary to place a blood sample on a reagent strip before placing it into the monitoring device to be read, and the lack of any reference to a

continuous glucose monitor means that such a monitor is not covered. (ECF No. 49 at 5-6.)

NCD 40.2 defines blood glucose monitors as "meter devices that read color changes produced on specially treated reagent strips by glucose concentrations in the patient's blood." LCD L27231 is not as explicit, but read in its entirety, the LCD is plainly focused upon a glucose monitor that involves a skin-piercing lancet to obtain a blood sample that is collected on a test strip. The Medicare Appeals Council was correct when it concluded that NCD 40.2 and LCD L27231 do not refer to or include continuous glucose monitors. (Tr. 27.)

However, the Secretary, through the Medicare Appeals Council, erred when it concluded that A47238 is incorporated into LCD L27231. Nothing in LCD L27231 attempts to incorporate A47238. The only connection between LCD L27231 and Article A47238 is that A47238 is listed under the "Related Documents" section of LCD L27231 (Tr. 586) and vice-versa (Tr. 593).

A policy article is distinct from an LCD. LCDs speak to the issue of whether a particular item or service is reasonable or necessary and therefore covered by Medicare. 42 U.S.C. § 1395ff(f)(2)(B); 67 Fed. Reg. 54534, 54536. Articles do not; their purpose is to address non-coverage information, like coding and payment. *See* CMS Medicare Manual System, Pub. 100-8, Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, § 13.1.3 - Local Coverage Determinations (LCDs), available at

http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf (last visited May 26, 2015). Presumably, when the preceding LMRP was converted into LCD L27231 and Article A47238, the relevant language explicitly excluding coverage for continuous glucose monitors could have been included in the LCD rather than the Article, or the LCD could have been amended at any subsequent point (the preceding LMRP does not appear to have been included as part of the record and therefore the court cannot be sure whether it addressed continuous glucose monitors at all). If the reference to the continuous glucose monitors contained in the Article had been included in the LCD, the outcome of this case likely would be different. But the fact that the LCD is silent as to whether continuous glucose monitors are covered is not a matter the court can overlook.

Looking to Articles for coverage determinations would undermine Section 522 of BIPA, whereby Congress created the right for certain beneficiaries to challenge coverage language contained in LCDs. *See* 68 Fed. Reg. 63692, 63693. Given their limited purpose, an Article is not subject to challenge. 42 C.F.R. § 426.325(b)(9). Reading an Article as if its language determined whether a service or item is covered would render such determination exempt from review. Moreover, Articles may be created without the notice and comment period required for an LCD. *See* CMS Medicare Manual System, Pub. 100-8, Medicare Program Integrity Manual, Chapter 13 – Local Coverage Determinations, § 13.7.2 – LCDs That Require a Comment and Notice Period, available

at http://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/pim83c13.pdf (last visited May 26, 2015). Accepting the Secretary's position that an Article can determine coverage would seemingly open the door to a system whereby beneficiaries would not have the opportunity to provide input on coverage determinations before the policy went into effect or to challenge those policies once they were adopted.

Nor does an Article fall within the scope of "CMS program guidance" so as to otherwise be entitled to substantial deference under 42 C.F.R. § 405.1062(a). Because NCD 40.2 and LCD L27231 do not reference continuous glucose monitors, and because Article A47238 is not incorporated into LCD L27231, the question is whether a continuous glucose monitor is reasonable and necessary for Whitcomb and not otherwise excluded.

The Secretary never undertook that analysis. Thus the court concludes that remand in accordance with 42 U.S.C. § 1395ff(b)(1)(A) and Sentence Four of 42 U.S.C. § 405(g) is necessary to permit the Secretary to assess this case under the proper legal standard. Finally, because this matter comes before the court based upon a request for pre-service authorization (Tr. 24), the court finds that 42 U.S.C. § 1395pp does not apply.

IT IS THEREFORE ORDERED that this matter is remanded to the Secretary for further proceedings in accordance with this decision. The Clerk shall enter judgment accordingly.

Dated at Milwaukee, Wisconsin this 26th day of May, 2015.

WILLIAM E. DUFFIN
U.S. Magistrate Judge